UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

BETTY PHELPS and DELBERT PHELPS,

Plaintiffs,

v.

WYETH, INC., et al.,

Defendants.

6:09-cv-6168-TC

ORDER AND FINDINGS AND RECOMMENDATION

COFFIN, Magistrate Judge:

Plaintiffs allege Betty Phelps developed tardive diskinesia–a debilitating neurological condition characterized by involuntary movements–due to taking a generic version of the prescription drug metoclopramide manufactured by Pliva[1] continuously from 2004 through 2007.[2]

[1]The Phelps initially sued several brand name and generic metoclopramide manufacturers. This court granted summary judgment on the Phelps' claims against defendants Wyeth, Schwarz and Alaven on June 21, 2010 (#83) and granted defendant Northstar's motion for summary judgment on April 24, 2012 (#296), leaving Pliva as the lone defendant in this action.

[2]The record shows that Ms. Phelps took the drug through 2009, but she developed her symptoms in 2007.

Plaintiffs original 2009 complaint alleged, among other things, that Pliva failed to adequately warn Ms. Phelps and her doctors about the dangers of long-term use of metoclopramide. In January 2011, I stayed this case pending the United States Supreme Court's decision in Pliva, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 rehearing denied, 2011 WL 35557247 (2011).

While this case was stayed, counsel for plaintiffs and defendant continued to litigate other metoclopramide cases. In February 2011, while reviewing discovery in another Pliva case, plaintiffs' counsel discovered copies of Pliva's metoclopramide product label that had been requested in the instant litigation, but never produced. These labels showed that Pliva did not update its generic metoclopramide product's labeling in 2003 and 2004 to include the warning on the brand-name product Reglan: **"THERAPY SHOULD NOT EXCEED 12 WEEKS IN DURATION."** Plaintiffs' counsel contacted Pliva's counsel who subsequently sent a letter to "Metoclopramide Plaintiffs' counsel" (which included plaintiffs' counsel) and to the Clerk of the United States Supreme Court notifying counsel and the Clerk that Pliva's metoclopramide product's label had differed from the brand-name drug Reglan's label for over five years. (#s 271-7, 271-9).

In June 2011, the United States Supreme Court issued its decision in Mensing, holding that federal law preempts state laws that impose a duty upon generic manufacturers like Pliva to change a drug's label. Mensing, 131 S. Ct. at 2567. Under Mensing, Pliva could not be liable for failing to warn plaintiffs of the dangers of long-term metoclopramide use so long as Pliva complied with the FDA regulations requiring a generic manufacturer to update the warning labels on its drug products to match the corresponding brand-name drug's label.

Pliva filed a supplemental motion to dismiss, arguing that, under Mensing, federal law preempted plaintiffs' failure to warn claims. (#188). Plaintiffs filed a supplemental motion for

partial summary judgment, alleging for the first time in their briefing a negligence per se claim against Pliva based on Pliva's alleged failure to comply with FDA regulations requiring generic manufacturers to update the warnings accompanying their drug products after the FDA approves changes for the corresponding brand-name drug. (#192). During the September 2011 oral argument on these motions, I noted that plaintiffs had raised their failure to update claim for the first time in their partial summary judgment briefing, and, because the label discrepancy was discovered two years after the complaint was filed, asked whether the failure to update claim was raised in plaintiffs' complaint. Plaintiffs' counsel responded that he believed the allegation was raised in the complaint, but requested leave to amend the complaint to more specifically allege the failure to update claim. (#236, p. 33:16-24).

I granted plaintiffs' subsequent motion to amend, and plaintiffs filed an amended complaint alleging that as well as being negligent for failing to adequately warn Ms. Phelps of the dangers of metoclopramide use, Pliva was also negligent for failing to update its generic metoclopramide product label in 2003 and 2004 to match the warning label on the brand-name product. (#s 240, 250, 251, 245, 255). Shortly after plaintiffs filed their amended complaint, I recommended that this court grant Pliva's motion to dismiss the failure to warn claims because they were preempted by Mensing and deny plaintiffs' partial summary judgment motion. (#260). In April 2012, the court adopted my findings and recommendation (#296), leaving this action to proceed on plaintiffs' allegations in their amended complaint that Pliva's negligence in failing to update its generic metoclopramide drug's warning labels in 2003 and 2004 injured Ms. Phelps.

Pliva then filed the instant motion for summary judgment on plaintiffs' failure to update claims. I heard oral argument on the motion and on the parties evidentiary objections on October

4, 2012.[3] The issue raised by this motion is not complex: does Oregon common law provide a remedy for injuries stemming from Pliva's alleged failure to update its warning label to match that of the brand-name product as required by federal law, and, if so, has plaintiff established a genuine issue of material fact regarding whether Pliva's failure to update caused Ms. Phelps's injuries. For the reasons discussed below, I find that Oregon law provides a remedy for Ms. Phelps's injuries and plaintiffs have established sufficient evidence of causation to survive summary judgment and recommend that this court deny Pliva's motion.

Standards

As the parties know from prior motions, summary judgment is appropriate if the record indicates that, taking the facts in a light most favorable to the nonmoving party, there is no genuine issue as to any material fact and the movent is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 24-48 (1986). Disputed facts notwithstanding, summary judgment is appropriate when federal law preempts a plaintiff's state law claim. Bank of America v. City and Cnty. of San Francisco, 309 F.3d 551, 566 (9th Cir. 2002).

Discussion

A. Viability of Plaintiffs' Claims Under Oregon Law

Pliva argues that plaintiffs' claim that it was negligent for failing to update the warning on its generic metoclopramide product in 2003 and 2004 to match the warning approved for use on the brand-name equivalent product fails for two reasons. First, Pliva asserts that plaintiffs do not allege that Oregon law requires a generic manufacturer to conform its drug labels to that of its brand-name equivalent and that the "failure to update" claim does not fall under Oregon's product liability

[3]I issued an order on the evidentiary objections on November 19, 2012. (#339).

statute–ORS 30.900. Next, Pliva argues that plaintiffs' allegation in their amended complaint that all metoclopramide warnings before 2009 (including the 2003 and 2004 warnings) were inadequate precludes any claim that Pliva was negligent in failing to update its 2003 and 2004 labels to match the brand-name warnings.

Here, plaintiffs argue that, in 2003 and 2004, Pliva failed to properly warn and instruct on the use of its product. For example, the 2004 label on the brand-name equivalent included bolded language warning that metoclopramide usage should not exceed twelve weeks in duration. (#308 at ¶ 63). Oregon's product liability statute provides that:

> product liability civil action means a civil action brought against a manufacturer...of a product for damages for personal injury...arising out of:
> ...
> (2) Any failure to warn regarding a product; or
> (3) Any failure to properly instruct in the use of a product.

ORS 30.900. The statute's plain language provides for actions against manufacturers of a product–including generic medication, for personal injury arising from failure to warn or instruct in proper usage of a product. This cause of action is distinct from the federal duty which arises out of federal law requiring that the warning labels of a brand-name drug and its generic copy must always be the same. Plaintiffs do not argue that Pliva is liable for failing to match its warning with that of the brand-name drug. Instead, they argue that Pliva is liable under Oregon law for failing to properly warn and instruct in the use of their product–failing to advise that a patient should not take the product for more than twelve weeks at a time. In short, the required language of the label stems from Food Drug and Cosmetics Act (FDCA) requirements (and, as Pliva notes, Mensing precludes actions asserting that under state law generic manufacturers had a duty to attach a warning more robust than that of the brand-name drug), but Oregon law provides for a cause of action for failing to include that

federally mandated warning and properly warn and instruct in the use of the generic product.

Further, Oregon law recognizes the doctrine of negligence per se, which provides that a statute or regulation may establish the standard of care a party is required to meet. To state a claim for negligence per se, a party must allege that (1) the defendant violated a statute; (2) plaintiffs were injured as a result of the violation; (3) plaintiffs were a member of the class intended to be protected by the statute; and (4) the injury suffered was the type that the statute was enacted to prevent. McAlpine v. Multnomah County, 131 Or. App. 136 (1994). Oregon courts have held that a plaintiff may allege a negligence per se cause of action against a drug manufacturer for failing to comply with FDA regulations. Axen v. American Home Products Corp. ex rel, 158 Or. App. 292, 307 (1999) ("evidence that [defendant] violated the regulations would be evidence that [defendant] breached the standard of care established by those regulations. If that breach could be shown to have caused [plaintiff's] injuries, then [defendant] could be liable under a common-law theory of negligence.").

Finally, Pliva's argument that because plaintiffs asserted that the metoclopramide product labeling was inadequate through 2009 they cannot contend that Pliva is liable under Oregon law for failing to provide those (allegedly) inadequate warnings in 2003 and 2004 is not persuasive. While Pliva is correct that Oregon does not recognize a "failure to inadequately warn" claim, this does not negate the fact that plaintiffs have set forth evidence establishing that Pliva did not include the federally mandated warnings on its products sold in Oregon in 2003 and 2004. A reasonable jury could conclude that Pliva did not meet the appropriate standard of care[4] and did not adequately warn or instruct in the use of its product.

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[4]As discussed in section B, the relevant federal regulations inform the standard of care and whether defendants met that standard. Hagan v. Gemstate Mfg, Inc., 148 Or. App. 192, 201 (1997).

Because plaintiffs' claim that Pliva was negligent for failing to update its metoclopramide product labels in 2003 and 2004 states a viable claim under Oregon law, I recommend that this court deny Pliva's summary judgment motion.

B. Plaintiffs' Standing to Bring and the Court's Jurisdiction to Consider Plaintiffs' Claims

Pliva argues that plaintiffs lack standing to pursue and this court lacks jurisdiction to consider a claim based on Pliva's alleged failure to update its 2003 and 2004 product warning labels. Relying on the Supreme Court's decision in Buckman v. Plaintiffs' Legal Comm., Pliva asserts that plaintiffs' claims are preempted because they are based solely on Pliva's alleged violation of the FDCA and there is no private right of action under the Act. Buckman, 531 U.S. 341 (2000). In Buckman, plaintiffs claiming to have suffered injuries from implantation of orthopedic bone screws brought suit alleging that the regulatory consultant to the bone screw manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws. The Supreme Court held that the plaintiffs' state law "fraud on the FDA claims" were preempted. Id. at 350. The Court explained:

> State-law-fraud-on-the-FDA claim inevitably conflict with the FDA's responsibility to police fraud consistently within the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 states' tort regimes will dramatically increase the burdens facing potential applicants–burdens not contemplated by Congress in enacting the FDCA....

Id. Pliva contends that allowing plaintiffs to pursue their state law negligence claim would "eviscerate" the FDA's discretion in determining whether and how to pursue alleged violations of federal law.

I find Buckman distinguishable from plaintiffs' state law negligence claims and find the Supreme Court's ruling in Medtronic v. Lohr persuasive. Medtronic, 518 U.S. 470 (1996). In

Medtronic, the plaintiff brought negligence and strict product liability claims against a pace maker manufacturer, alleging defective design and failure to warn and relying in part on the manufacturer's alleged violation of FDA regulations. Id. The defendants maintained that the FDA's regulation of the pacemaker manufacturer through the approval process preempted plaintiffs' state law claims. The Supreme Court disagreed, holding that "the presence of a state-law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but 'merely provides another reason for manufacturers to comply with...federal law.'" Buckman, 531 U.S. at 351 (summarizing and quoting Medtronic, 518 U.S. at 513); see also Medtronic, 518 U.S. at 495 ("nothing in § 360k denies Florida the right to provide a traditional damages remedy for violation of common-law duties when those duties parallel federal requirements."). Further, the Medtronic, claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements.[5]

Similarly, in this case, plaintiffs' claims arise from Pliva's alleged failure to use reasonable care in updating its metoclopramide product warning labels, not from violations of FDCA requirements. Plaintiffs' invoke relevant federal regulations to inform, rather than to create, the standard of care and whether defendants met that standard. Hagan, 148 Or. App. at 201 (1997); see also Axen, 158 Or. App. at 307 ("evidence that [defendant] violated the regulations would be

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[5]The issue presented here is also analogous to signs at railroad crossings. Negligence claims based on inadequacy of crossing warning devices are preempted by federal law where devices are installed pursuant to and in compliance with federal regulations. 45 U.S.C. § 434. Negligence claims against a railroad are not, however, preempted where the crossing was not surveyed by a diagnostic team and the Federal Highway Administration (FHWA) approval was never finalized. Eldridge v. Missouri Pacific R.R., 832 F.Supp. 328 (E.D. Okl. 1993).

evidence that [defendant] breached the standard of care established by those regulations. If that breach could be shown to have caused [plaintiff's] injuries, then [defendant] could be liable under a common-law theory of negligence."). I find that plaintiffs have standing to bring and this court has jurisdiction to decide plaintiffs' state law negligence claims which are based on Pliva's alleged failure to update its product's warning labels in 2003 and 2004.

C. Preemption of Failure to Update Claim based on Presentation to Other Courts

Pliva next argues that plaintiffs' failure to update claim is preempted because the same argument was presented to and rejected by the United States Supreme Court, the Eighth and Sixth Circuits and various district courts.

The failure to warn claim was "brought to the Supreme Court's attention in Mensing" by a letter from Pliva's counsel to the Court's Clerk. (#302 at 18). Despite the letter, the issue was not raised at oral argument or discussed in Mensing's majority or dissenting opinions. (Id.) The issue was presented to the Sixth Circuit in supplemental briefing and in an petition for rehearing and rehearing en banc. The Sixth Circuit panel, however, denied rehearing, concluding that "the issues raised in the petition were fully considered upon the original submission and decision of the cases." (Id. at 19). Plaintiffs in Mensing v. Wyeth, Inc., presented the issue to the Eighth Circuit in a "motion for leave to file a [sic] supplemental briefing," which the Eighth Circuit denied before entering judgment affirming the dismissal of generic drug manufacturer defendants. Mensing v. Wyeth, Inc., 2011 WL 4636653 (8th Cir. Sept. 29, 2011). Pliva interprets these courts' lack of consideration of the failure to warn claims raised by letter, supplemental briefing or various motions as implicitly holding that the generic defendant's alleged failure to update its label was considered and found not to alter the preemptive effect of Mensing.

Letters and briefing submitted to a court do not constitute binding (or persuasive) authority and provide no assistance to this court. Moreover, "[q]uestions that merely lurk in the record, neither brought to the attention of the court, nor ruled upon, are not to be considered as having been so decided as to constitute precedent." Webster v. Fall, 266 U.S. 507, 511 (1925). To the extent that Pliva argues that the failure to update claim was "brought to the attention" of the Supreme Court and the two Circuit courts, this argument is not persuasive. In each instance, the issue was raised in a letter and in a request for supplemental briefing or rehearing. In other words, the issue was not raised in the scheduled briefing but was raised as an afterthought in litigation already proceeding. Although the failure to update claim "lurked in the record" in cases before the United States Supreme Court and the Sixth and Eighth Circuits, these cases did not address nor decide the issue so as to be binding on this court. Id. see also Nemire v. Mitsubishi Motors Corp., 381 F.3d 540, 559 (6th Cir. 2004).

Pliva also argues that plaintiffs' failure to update claim is preempted because it was rejected by a number of district courts. See e.g. Brinkley v. Pfizer, Inc., 2012 WL 1564945 (W.D. Mo. April 12, 2012); Fulgenzi v. Pliva, Inc., __F.Supp. 2d___, 2012 WL 1110009 (N.D. Ohio March 31, 2012); Gross v. Pliva, Inc., 825 F.Supp.2d 654, 660 (D.Md 2011). Decisions of other district courts maybe persuasive, but they are not binding on this court. Moreover, I have reviewed these decisions and do not find them persuasive.

In Fulgenzi, for example, the plaintiff brought suit alleging that she developed tardive dyskinesia after taking metoclopramide for an extended period. Fulgenzi, 2012 WL WL 1110009 * 5. "At the core of all Fulgenzi's claims [was] the basic assertion that the drug manufacturers should have provided warnings alerting doctors and patients to the heightened risk of developing

neurological complications from long-term use of metoclopramide." Id. In her amended complaint the plaintiff asserted various claims under Ohio common law, including negligence. Id. at 7. The Fulgenzi court noted that the plaintiff alleged that "defendant manufacturers failed to 'include the FDA approved warning against therapy in excess of 12 weeks that was included in [the brand-name equivalent's] warning labels.'" Id. at *8. The court, however, concluded that there was "no requirement under Ohio law that a generic manufacturer's label mirror" that of the brand-name label, "that there was "no private cause of action for violations of FDA regulations," and that the failure to warn claim was "implicitly rejected" by the Sixth Circuit in Smith v. Wyeth." Id. at *8-9.

I find the Fulgenzi reasoning regarding Ohio common law unpersuasive and inconsistent with the Oregon law. As previously discussed, plaintiffs here bring a claim under Oregon law alleging that Pliva was negligent for failing to update its product's warning labels in 2003 and 2004. The relevant federal law is used only to inform the standard of care. Moreover, as discussed above, I cannot follow Fulgenzi's holding and construe the Sixth Circuit's failure to consider the failure to update claim that was raised in supplemental briefing as an "implicit rejection" of this claim.

I find that presentation of the failure to warn claim in supplemental briefing, motions for re-hearing, and letters to various courts does not preempt plaintiffs from moving forward with their failure to update claim.

D. Causation of Injuries by Failure to Update Labeling

Pliva argues that plaintiffs failure to update claim fails because they cannot establish that the alleged failure to update caused Ms. Phelps's injuries because there is no evidence that Ms. Phelps's doctors read the Pliva's metoclopramide label. Relying on Benjamin v. Wal-Mart Stores, Inc., Plaintiffs argue that reliance on or reading of the warning label is not an element of their claims.

Benjamin, 185 Or. App. 444, 454 (2002)[6] ("A warning's adequacy is a proper subject of expert testimony" and is "ordinarily a jury question."). Benjamin also stated that it was not "significant that the evidence does not show that [the injured party] actually read the warning on the heater" as there was evidence that "one of the ways in which the warning was defective was that its design was insufficient to draw a user's attention." Id. at 460. I note that I rely on this case for the proposition that sufficiency of warnings is an expert and jury question. Id. at 460. I am mindful that there is no claim (nor could there be under Mensing) in this case that Pliva is liable for the sufficiency of the warning's design. A reasonable juror could find, however, that the warning on the brand-name metoclopramide which stated in bold and all capital letters: **"THERAPY SHOULD NOT EXCEED 12 WEEKS IN DURATION"** would have been "noticed, read, and heeded" by Ms. Phelps (or her doctors). Thus, a reasonable juror could find that Pliva was negligent in failing to update its label to match the bolded and all capitalized brand-name warning and that the failure was the legal cause of Ms. Phelps' injuries.

E. ORS 30.910 Rebuttable Presumption

Pliva argues that it is entitled to summary judgment on plaintiffs' product liability claim because plaintiffs cannot rebut the presumption that the generic metoclopramide product as "manufactured and sold or leased [was] not unreasonably dangerous for its intended use." Pliva specifically points out that none of plaintiffs' experts have opined that its metoclopramide product was unreasonably dangerous and note that Ms. Phelps use of the product for more than 12 weeks was

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[6] I note that Motus v. Pfizer, Inc., upon which Pliva relies in arguing that where a warning is not read, any inadequacy in the warning cannot be the cause of the alleged injury relied on California substantive law. Motus, 358 F.3d at 660. Thus, this case is not instructive in analyzing plaintiffs' Oregon law claim.

an "off-label use."[7] Review of the summary judgment record reveals that Ms. Phelps's doctors testified that they did not understand that use longer than 12 weeks was an "off-label use." (#308 at ¶ 9.) Further, Ms. Phelps began using metoclopramide in 2002 and there is no support in the record for the argument that prior to 2004 use of metoclopramide for longer than 12 weeks was an "off-label" use. (Id. at ¶¶ 60-63 (discussing the changes made to the brand-name Reglan's label in 2004 to warn that metoclopramide **"THERAPY SHOULD NOT EXCEED 12 WEEKS IN DURATION.**"). In short, I find that plaintiffs have set forth enough evidence to rebut the presumption that Pliva's product was not unreasonably dangerous for its intended use.

F. General and Specific Causation

Pliva argues that it is entitled to summary judgment because plaintiffs cannot establish general or specific causation. As Pliva points out, when causation involves complex medical questions, Oregon law requires expert testimony of a reasonable probability of causation before a case may proceed to trial. Chouinard v. Health Ventures, 179 Or. App. 507, 512 (2002). The summary judgment record includes testimony from multiple physicians (and Pliva's own experts) that metoclopramide use may cause tardive dyskinesia. (#308 at ¶ 32). I find that plaintiffs have established expert testimony that there is a reasonable medical probability that Pliva's alleged failure to update its warning label caused Ms. Phelps's injury.

Oregon law requires that a plaintiff establish specific causation by providing expert testimony that the product at issue caused the plaintiff's condition to a reasonable medical probability. Joshi v. Providence Health System of Oregon Corp., 198 Or. App. 535, 512 (2005) (discussing whether

[7]When a drug is used in a different way than described in the FDA-approved drug label, it is said to be an "off-label use." http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

the expert testified that causation was probable or merely possible). Here, plaintiffs include evidence that Ms. Phelps's treating neurologist determined that Ms. Phelps's "Parkinsonian symptoms were most likely related to her metoclopramide usage." (#308 at ¶¶ 17-18). Another treating physician–a movement disorder specialist from Oregon Health and Sciences–opined that Ms. Phelps suffers from tardive dyskinesia caused by her metoclopramide usage and used Ms. Phelps's case as an example of movement disorders caused by the drug in a presentation on metoclopramide's propensity to cause movement disorders. (Id. at ¶¶ 22-23). In short, I find that plaintiffs have presented evidence of cause-in-fact that has the "quality of reasonable probability" that Pliva's product was the cause of Ms. Phelps's injuries. Joshi, 198 Or. App. at 545.

Because a rational juror could find that plaintiff established general and specific causation, this court should deny summary judgment on this issue.

G. Punitive Damages

Finally, Pliva argues that this court should grant summary judgment on plaintiffs' punitive damages claim because ORS 30.927 prohibits a punitive damages award here because the FDA approved Pliva's metoclopramide product. The relevant statute provides that a manufacturer shall not be liable for punitive damages if the drug:

> [w]as manufactured and labeled in relevant and material aspects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration under the Federal Food, Drug and Cosmetic Act or the Public Health Service Act;

ORS 30.927(1)(a). I do not agree with Pliva's assertion. As plaintiffs point out, the very reason that their failure to update claim survives Mensing is that Pliva allegedly failed to update its product's label in 2003 and 2004 to match that of the brand-name equivalent as required by relevant federal

regulations. Thus, its product was not labeled in accordance with the "the terms of an approval or license issued by" the FDA. I recommend that the court deny Pliva's motion for summary judgment on plaintiffs' punitive damages claim.

Conclusion

I recommend that this court deny Pliva's motion for summary judgment. (#301).

The above Findings and Recommendation will be referred to a United States District Judge for review. Objections, if any, are due no later than fourteen days after the date this order is filed. The parties are advised that the failure to file objections within the specified time may waive the right to appeal the District Court's order. Martinez v. Ylst, 951 F.2d 1153 (9th Cir. 1991). If no objections are filed, review of the Findings and Recommendation will go under advisement on that date. If objections are filed, any party may file a response within fourteen days after the date the objections are filed. Review of the Findings and Recommendation will go under advisement when the response is due or filed, whichever date is earlier.

DATED this 19th day of December 2012 .

THOMAS M. COFFIN
United States Magistrate Judge